Nos. 2022-1293, 2022-1294, 2022-1295, 2022-1296

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

IN RE: CELLECT, LLC,

Appellant.

Appeals from the United States Patent and Trademark Office,
Patent Trial and Appeal Board, in *Ex Parte* Reexamination Nos.
90/014,453, 90/014,454, 90/014,455, 90/014,457

BRIEF OF *AMICUS CURIAE* NOVARTIS PHARMACEUTICALS CORPORATION IN SUPPORT OF APPELLANT'S REQUEST FOR REHEARING EN BANC

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 22-1293, 22-1294, 22-1295, 22-1296

Short Case Caption In re: Cellect, LLC

Filing Party/Entity Amicus Curiae Novartis Pharmaceuticals Corporation

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Date: 11/27/2023

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Name: Jane M. Love, Ph.D.

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Novartis Pharmaceuticals Corporation		Novartis AG

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☐ Yes (file separate notice; see below) ☐ No ☑ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

I. STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

Novartis Pharmaceuticals Corporation is a science-based global healthcare company that seeks to extend and improve patients' lives. Novartis's products include innovative small and large molecule medicines, cell and gene therapies, and radiopharmaceuticals. Those products reached over a quarter billion patients in 2022 alone, treating diseases in the fields of cardiology, hematology, oncology, immunology, neuroscience, ophthalmology, respiratory illness, and rare genetic disorders. Many of these products embody breakthroughs in medical innovation that have transformed the treatment of disease. Novartis's work and mission rely heavily on patents, which provide the core incentive that enables the company to sustainably invest and reinvest billions in innovative R&D year after year. Novartis has litigated double-patenting issues previously, including before this Court.

[1] Under Federal Rule of Appellate Procedure 29(a)(4)(E), counsel for Novartis represent that no counsel for a party in this case authored this brief in whole or in part, and that no person or entity, other than Novartis or its counsel, contributed money intended to fund the preparation or submission of this brief. Appellant consents to, and the Director of the USPTO does not oppose, the filing of this brief.

II. INTRODUCTION

Novartis believes that the appeal was incorrectly decided as other *amici* explain, but submits this amicus brief to address why the Court, if the panel decision is not reversed outright, should rehear to address terminal disclaimers.

Patent applicants can file terminal disclaimers to resolve obviousness-type double-patenting (ODP) rejections during prosecution. The applicant disclaims any term in a new patent longer than the term of an earlier-issued patent. That aligns the patent terms and permanently links the patents so they must be commonly owned, effectively bundling their claims together. In other words, the second patent becomes encumbered with obligations tying it to the first patent as a matter of law.

In *Cellect*, no terminal disclaimers had been filed for patents that were obvious variants of each other. The panel found that all the patents should expire when the first patent in the family did, even though the later expiration dates were due only to patent term adjustments (PTA). *In re: Cellect, LLC*, 81 F.4th 1216, 1223–29 (Fed. Cir. 2023). That has led some parties to argue, incorrectly, that patents expiring later due to PTA are *always* invalid under *Cellect* in view of earlier-expiring obvious variant patents. Within a month of the panel decision, a Delaware district court invalidated a PTA-extended patent based on "the rule dictated in *In re Cellect,*" which that court held "recognizes no exception[.]" *Allergan USA, Inc. v. MSN Labs. Priv. Ltd.*, No. 19-1727-RGA, 2023 WL 6295496, at *22 (D. Del. Sept. 27, 2023).

Such an expansive reading of *Cellect*, if allowed to stand, would upend terminal disclaimer practice. *Cellect* does indeed provide for an "exception"—it states that terminal disclaimers are the "solution" to the ODP "problem[.]" 81 F.4th at 1228. So, for instance, when a child patent is terminally disclaimed against a parent, that resolves the ODP issue as between those patents, regardless of whether the child expires first. Otherwise, a patent with PTA would always be at risk of being held invalid for ODP in view of earlier-expiring continuation or other patents.

If the Court does not reverse *Cellect* outright, it should at least clarify that *Cellect*'s holding does not compel the *Allergan* result. A terminal disclaimer filed to address ODP as between two patents completely resolves any double-patenting problem—regardless of whether one patent expires later. The claims have been effectively bundled together by the filing of the terminal disclaimer. The Court invalidated the *Cellect* patents only because *no* terminal disclaimers had been submitted in the entire patent family. The Court should clarify this critical issue now to prevent a harmful shift in terminal disclaimer practice—a shift that would deprive patent owners of lawful PTA and confuse patent owners and the public about when exclusivity over an invention expires.

III. ARGUMENT

A. Terminally Disclaiming One Patent Against Another Resolves Any Obviousness-Type Double-Patenting Problem.

ODP seeks to prevent an inventor from securing "a second, later-expiring patent for non-distinct claims." *Cellect*, 81 F.4th at 1226. It also prevents "harassment" of alleged infringers "by multiple assignees." *In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009).

Under 35 U.S.C. § 253, an applicant can overcome an ODP rejection by disclaiming the terminal part of any patent that would extend beyond the expiration date of an earlier-issued patent. *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1213 (Fed. Cir. 2014); *see also* 37 C.F.R. § 1.321(c)(3) (terminal disclaimer provision); *see also Manual of Patent Examining Procedure* ("MPEP"), § 804 (9th ed. Rev. 7, Feb. 2023). "Terminal disclaimers are almost always filed to overcome an ODP rejection," and are thus "inextricably intertwined" with ODP. *Cellect*, 81 F.4th at 1228.

As between two pending applications with obvious variant claims, the Patent Office will provisionally reject both and require a terminal disclaimer to be submitted for the later-issuing patent, limiting its term to that of the first patent. *See* MPEP, § 804.I.B. As between an issued patent and a pending application, the Office will insist on a disclaimer that limits the second patent's term to that of the first patent. *See* MPEP, § 804.I.A. In other words, an inventor receives only the term of

the first-issued patent, whether that term is longer or shorter than the second patent's term.

Thus, when an inventor terminally disclaims a second patent to have no more term than a first-issued patent, any ODP concerns are resolved. Once a terminal disclaimer has been filed, the applicant has effectively received a single set of claims to a single invention that will expire no later than a single expiration date. *See Application of Braithwaite*, 379 F.2d 594, 601 (C.C.P.A. 1967).

B. *Cellect* Should Be Read to Comport with Established Terminal Disclaimer Practice.

Cellect itself states that terminal disclaimers are the "solution" to the ODP "problem[.]" 81 F.4th at 1228. The *Cellect* opinion, however, does not explicitly state that terminally disclaiming a second-issued patent against a first-issued patent insulates both patents from a future ODP challenge, regardless of their relative expiration dates. That silence creates unnecessary confusion.

The Court in *Cellect* invalidated a parent (first-issued) patent (the '369 patent) based on an earlier-expiring child patent (the '036 patent), and the opinion was marked precedential. This has led some to argue that *Cellect* represents a sea change in patent practice. On this view, a parent patent that expires later than an obvious-variant child patent due to PTA would always be invalid for ODP.[2] Advocates for

[2] Novartis is aware of at least the following district court cases where this broad view of *Cellect* has been raised: *Allergan*, 2023 WL 6295496, at *21–22; and MSN's

this view read *Cellect* as requiring that a later-expiring parent patent due to granted PTA be disclaimed against any earlier-expiring child patents to avoid ODP—even if the child patents had already been terminally disclaimed against the parent. In practice, this would require submitting terminal disclaimers in *both* the child and parent patents.

That result would be contrary to established terminal disclaimer practice—and it simply makes no sense. The patents in this scenario were *already bundled together* through the first terminal disclaimer. Requiring additional terminal disclaimers would just deprive the patent owner of its statutory right to PTA.

That courts may misread *Cellect* in this manner is not hypothetical. In *Allergan*, one of two child patents (the ’709 patent) was used as an ODP reference against a parent patent, even though the child had already been terminally disclaimed against the parent. *See* Ex. B to Joint Status Report on the Impact of *In Re Cellect* on Claim 40 of the ’356 Patent, *Allergan*, 2023 WL 6295496, (D. Del. Sept. 6, 2023), ECF No. 482-1. The court found that *Cellect* rendered the later-expiring parent patent invalid, without any analysis of how terminal disclaimers addressed the ODP problem. *Allergan*, 2023 WL 6295496, at *21–22. In reaching that conclusion, *Allergan* found that *Cellect* “recognizes no exception to the rule it announced,

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Mot. for Leave to Respond to Pl.’s Notice of Subsequent Authority, *Acadia Pharms. Inc. v. Aurobindo Pharma Ltd.*, No. 20-985-GBW (D. Del. Oct. 4, 2023), ECF No. 273.

whether for first-filed, first-issued claims or otherwise." *Id.* at *5, *21; *see also id.* at *22

This result, however, is illogical; the child and parent patents had already been effectively bundled together through the terminal disclaimer into a single set of claims that would expire no later than the parent patent's expiration date. *Cellect* merely held that PTA is to be accounted for when analyzing ODP. The *Allergan* reading of *Cellect* is incorrect for several reasons, as this Court should clarify.

First, according to the panel itself, the use of terminal disclaimers in *Cellect* to link the child and parent patents would have resolved the ODP in that case. *Cellect*, 81 F.4th at 1228–29. In *Cellect*, the patentee filed continuation applications without terminal disclaimers and was granted PTA based on greater Patent Office delays in some applications as compared to others. Since all patents were expired at the time of litigation, it was no longer possible to file terminal disclaimers. But any ODP problem would have been avoided if the child patents had been terminally disclaimed against the parent (the '369 patent). In that scenario, the patentee would not have received additional term beyond the initial 45 days of PTA granted to the parent. *Id.* at 1219–20. All other patents would have been terminally disclaimed against the parent no matter how much PTA they received, and common ownership among all patents would have been maintained.

Second, a broad interpretation of *Cellect* would deprive patent owners of PTA guaranteed by statute. Under current law, the statutory term authorized for an invention *includes* any term added through PTA. *See* 35 U.S.C. § 154(b). But a patent owner would have to disclaim duly awarded PTA on a broad view of *Cellect*. That would unfairly deprive the patentee of the additional patent term to which it is entitled by statute. To avoid that result, *Cellect* should be clarified to state that one terminal disclaimer that disclaims a later granted patent against an earlier granted patent resolves all ODP issues as between those patents. No additional disclaimers are needed. That would preserve the applicant's lawful PTA while preventing the acquisition of additional PTA in related patents.

Third, a broad view of *Cellect* would undermine both patentees' and the public's certainty in assessing when a patentee's right to exclude ends. For example, under the *Allergan* court's interpretation of *Cellect*, a parent patent with PTA would always be at risk of being invalidated for ODP by a child patent with less term. That risk would depend on the vagaries of Patent Office delays in processing different applications.

The patent system, however, should reliably and predictably inform the patentee and the public when a patent expires, allowing the invention to transfer to the public domain at the end of the patent term. *See, e.g.*, *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989). When all child patents are

terminally disclaimed against the parent patent, that certainty exists: the parent's term controls the entire patent family's term. But if patent owners must constantly evaluate whether a second-issued patent has received less term than a first-issued patent to disclaim to the shortest term, that certainty would end.

Fourth, a broad interpretation of *Cellect* would discourage, and even punish, continuing application practice where a parent patent issued with PTA. Under 37 C.F.R. § 1.53(b), a patentee may file a continuing application during the pendency of another application. *Transco Prods. Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 555 (Fed. Cir. 1994); *see also* MPEP, §§ 201.06–201.08. Patentees typically use continuing applications to claim a similar invention as an earlier application, but with "some variation in the scope of the subject matter claimed." *Transco*, 38 F.3d at 555. The continuing application is then afforded the benefit of the parent application's filing date as to the common subject matter. *See id.* at 556. This well-established patent prosecution practice is legitimate, lawful, and is a critical feature of the patent system that enables innovators to refine claims to their inventions without losing their rights.

Under a broad interpretation of *Cellect*, however, a patentee would be disincentivized from filing continuing applications in view of the substantial risk of the parent patent being invalidated for ODP over a child patent. Such a rule would

discourage innovation and punish patentees for exercising their statutory rights to prosecute continuing applications and to receive PTA where appropriate.

C. The Court Should Clarify *Cellect* Given the Erroneously Broad View Taken in *Allergan*.

Novartis believes that *Cellect* was wrongly decided. But even if the Court concludes that the panel correctly decided the case on those unique facts, it should clarify that a single terminal disclaimer that disclaims a later granted patent against a commonly-owned earlier granted patent resolves the ODP problem as between those patents. *See, e.g.*, Fed. R. App. P. 35(b)(1)(B) (rehearing en banc is appropriate to resolve "question[s] of exceptional importance"). Put differently, *Cellect* should have limited application beyond its unusual facts: there were no terminal disclaimers or disputes on obviousness, and all patents were expired. This clarification would limit the harm from broadly interpreting *Cellect* as reflected in the *Allergan* decision.

Absent action by the Court now, parties may need to wait years for clarification. In the meantime, patent owners will be forced to disclaim parent patents with PTA or run the risk of invalidation by ODP. The stakes are high, as PTA can add years to a patent's term. In the pharmaceutical industry, this additional term reflects value that may fund research into life-saving medicines. The Court should intervene to prevent the severe harm to patent holders that would result from an expansive reading of *Cellect*.

Dated: November 27, 2023

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(b)(4) and the rules of this Court. This brief contains 2,317 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).

2. Pursuant to Federal Rule of Appellate procedure 29(a)(4), (b)(4) and the rules of this Court, this brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2019 in Times New Roman, 14-point.

Dated: November 27, 2023

/s/ Jane M. Love
Jane M. Love, Ph.D.